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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/018,194	02/04/1998	BARBARA A. GILCHRIST	BU94-15A2	9447

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EXAMINER

WEGERT, SANDRA L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/018,194

Applicant(s)

GILCHRIST ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of Application, Amendments, and/or Claims

The Amendment, sent 24 October 2005, has been entered into the record.

Claims 1-73 are canceled. Claims 74-77 are new. Claims 74-77 are under examination in the Instant Application.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Withdrawn Objections And/or Rejections

Claim Rejections - 35 U.S.C. § 112, First Paragraph, Scope of Enablement.

The rejection of Claims 57-61 and 63-73 and new claims 74-77 under 35 U.S.C. 112, first paragraph, "scope of enablement" is *withdrawn*. This rejection was made in the previous Office Action (pages 3-6, 6 June 2005) for claims that had read on a method of inhibiting all kinds of hair loss. Applicants cancelled claims 57-61 and 63-73. Furthermore, Applicants have replaced the word "vertebrate" with "mammal" in newly-submitted claims, thereby reciting only those animals that are able to grow hair (page 4, 6 June 2005).

-35 USC § 112, second paragraph, indefiniteness.

The rejection of Claims 57, 63 and 69 under 35 U.S.C. 112, second paragraph, for being indefinite is *withdrawn*. Applicants cancelled Claims 57, 63 and 69 (24 October 2005). New claims do not recite the phrase: "a biologically active" fragment of nerve growth factor.

New/Maintained Objections And/or Rejections

Typographical

New Claim 74 is objected to for reciting the peptide "KGK," rather than the elected peptide "KGA," as encompassed by SEQ ID NO: 4, 9 and 10.

Claim Rejections: Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 74-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 2 and 19, respectively, of U.S. Patent No. 6,103,689. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

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Instant Claims 74-77 are drawn to a method of delaying hair loss in a mammal using a biologically active fragment of NGF (SEQ ID NO: 4, 9, 10 or "KGA"). Instant Claims 74-77 are drawn to a method of inhibiting apoptosis in keratinocytes by administering a biologically active fragment of nerve growth factor. Claim 2 of the '689 patent is drawn to a method of inhibiting apoptosis in keratinocytes using a ligand selected from a group that includes a biologically active fragment of nerve growth factor. Instant Claims 74-77 are therefore obvious over claim 2 of the '689 patent because they merely narrow the scope of that claim.

Claim 19 of the '689 patent is drawn to a method of inhibiting human epidermal keratinocyte cell loss using a ligand selected from a group that includes a biologically active fragment of nerve growth factor. The specification of the '689 patent teaches that inhibition of keratinocyte and melanocyte cell loss results in the delay of hair loss and graying (column 2, lines 52-62). It would thus be obvious to the artisan of ordinary skill to administer biologically active fragments of NGF as claimed in claim 19 of the '689 patent in order to inhibit hair loss as claimed in instant Claims 74-77, because the artisan would expect just such a delay to result from the inhibition of keratinocyte cell loss.

Conclusion

Claims 74-77 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.


The fax number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about

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the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

4 February 2006


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
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